In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-0625V
UNPUBLISHED

KATHERINE SHOEMAKER,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: January 18, 2022

Special Processing Unit (SPU); Dismissal; Onset; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

David A. Kulwicki, Mishkind Kulwicki Law CO LPA, Cleveland, OH, for Petitioner.

Christine Mary Becer, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION[1]

On May 20, 2020, Katherine Shoemaker filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that she suffered a right shoulder injury related to vaccine administration ("SIRVA") caused-in-fact by the influenza ("flu") vaccine she received on September 24, 2018. Petition at ¶¶ 2-3.

For the reasons set forth below, I hereby DENY entitlement in this case. Petitioner has failed to provide any evidence to support her assertions. She has failed to establish that her injury meets the definition for a Table SIRVA, and cannot otherwise make a sufficient preponderant showing for non-Table vaccine causation.

[1] Because this unpublished Decision contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all Section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Procedural History

Along with her petition, Ms. Shoemaker filed her affidavit, PAR questionnaire listing all medical providers seen, vaccine record, and some of the medical records required under the Vaccine Act. Exhibits 1-7; Section 11(c) (regarding the medical records required under the Act). In her affidavit, Petitioner further asserted that after receiving this vaccination, she "immediately started having a deep ache in [her] right deltoid muscle which continues to this day." Exhibit 1 at ¶ 5. However, the medical records show Petitioner did not seek treatment for her right shoulder pain until July 15, 2019, almost ten months post-vaccination. Exhibit 3 at 8. Additionally, the vaccine record did not indicate the site or method of vaccination. Exhibit 2.

After being ordered to provide a vaccine record which specified the site of vaccination, Petitioner filed a supplemental affidavit indicating that she had "obtained and reviewed records from the subject Meijer Pharmacy . . . [which] do not document in which arm the vaccine was administered." Exhibit 8 at ¶ 3. However, she did not provide these records. She added that she "contacted the subject Meijer Pharmacy and was informed that the store does not have a set policy as to which arm vaccines are administered . . . [and that] the location is left to customer preference." *Id.* at ¶ 4. The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

During the initial status conference held on July 21, 2020, the parties discussed the lack of documentation showing the site of vaccination and the approximately ten-month delay between vaccination and when Petitioner first sought treatment for her right shoulder pain. ECF No. 13. Petitioner was ordered to file additional evidence to address these deficiencies. *Id.*

More than six months later, on February 10, 2021, Petitioner filed a third affidavit providing reasons for the delay and detailing her efforts to obtain further vaccine documentation and medical records from her gynecologist. Exhibits 9-10. She attributed the delay to her reaching the age where she was no longer able to see her pediatrician – along with her inability to obtain a new primary care provider, her schedule as a nursing student, and her concern that reporting her injury would affect any future employment as a nurse. Exhibit 9 at 3-4, 6-10. The medical records do show Petitioner failed to mention her right shoulder pain during an October 17, 2018 visit to her gynecologist, approximately three weeks post-vaccination. Exhibit 10 at 7-10.

On June 1, 2021, Respondent filed his Rule 4(c) Report opposing compensation. ECF No. 19. He indicated that his position was based upon the fact that "[P]etitioner's first report of pain was ten months after vaccination." *Id.* at 4 (emphasis in the original).

Thereafter, Petitioner was granted subpoena authority to obtain the complete vaccine record from Meijer Pharmacy. ECF No. 21. On July 14, 2021, Petitioner filed the documentation obtained through subpoena, which included a consent form that failed to indicate the site of vaccination. Exhibit 11 at 18.[3]

On August 10, 2021, I issued an order to show cause. ECF No. 23. Petitioner filed a response on September 9, 2021. ECF No. 24. The matter is now ripe for adjudication.

II. Applicable Legal Standards

Under Section 13(a)(1)(A) of the Act, a petitioner must demonstrate, by a preponderance of the evidence, that all requirements for a petition set forth in section 11(c)(1) have been satisfied. A petitioner may prevail on her claim if the vaccinee for whom she seeks compensation has "sustained, or endured the significant aggravation of any illness, disability, injury, or condition" set forth in the Vaccine Injury Table (the Table). Section 11(c)(1)(C)(i). The most recent version of the Table identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). The Table injury of SIRVA following receipt of an influenza vaccine was added in 2017.[4] If a petitioner establishes that the vaccinee has suffered a "Table Injury," causation is presumed.

[3] It appears Petitioner mistakenly dated her signature as provided on September 7, 2018. Exhibit 11 at 18. However, other entries, including the signature of the vaccine administrator, use the correct date of September 24, 2018. *Id.* at 17-18.

[4] Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV) (2017). The criteria establishing a SIRVA under the accompanying *Qualification and Aids to Interpretation* ("QAI") are as follows:

> *Shoulder injury related to vaccine administration (SIRVA).* SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

If, however, the vaccinee suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, petitioner must prove that the administered vaccine caused injury to receive Program compensation on behalf of the vaccinee. Section 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, petitioner must prove her claim by preponderant evidence. Section 13(a)(1)(A). This standard is "one of . . . simple preponderance, or 'more probable than not' causation." *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1279-80 (Fed. Cir. 2005) (referencing *Hellebrand v. Sec'y of Health & Human Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993). The Federal Circuit has held that to establish an off-Table injury, petitioners must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999). *Id.* at 1352. The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Federal Circuit has indicated that petitioners "must show 'a medical theory causally connecting the vaccination and the injury'" to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface*, 165 F.3d at 1352-53 (quoting *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that "[t]here must be a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury.'" *Id.* The Federal Circuit subsequently reiterated these requirements in its *Althen* decision. *See* 418 F.3d at 1278. *Althen* requires a petitioner

> to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of *Althen* must be satisfied. *Id.*

> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

Finding a petitioner is entitled to compensation must not be "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." Section 13(a)(1). Further, contemporaneous medical records are presumed to be accurate and complete in their recording of all relevant information as to petitioner's medical issues. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). Testimony offered after the events in questions is considered less reliable than contemporaneous reports because the need for accurate explanation of symptoms is more immediate. *Cucuras*, 993 F.2d at 1528 (noting that "the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight"); *Reusser v. Sec'y of Health & Human Servs.*, 28 Fed. Cl. 516, 523 (1993); *Vergara v. Sec'y of Health & Human Servs.*, No. 08-882V, 2014 WL 2795491, at *4 (Fed. Cl. Spec. Mstr. July 17, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recounted in later medical histories, affidavits, or trial testimony.").

III. Analysis

As I informed Petitioner in the Order to Show Cause, the record lacks evidence needed to support her claims. ECF No. 23. Specifically, she has failed to provide evidence to counter the inferences derived from her ten-month delay in seeking treatment, or to show her condition during that time. *Id.* Petitioner in reaction has filed barely two pages that reiterate the evidence already contained in the record of the case, and otherwise arguing that an expert report is not needed for causation. Response, filed Sept. 9, 2021, ECF No. 24. She maintains that she "has shown that her claim should not be dismissed . . . and that [her] claim should be maintained within SPU." *Id.* at 2.

The record in this case still shows that Petitioner did not seek medical care for her alleged SIRVA until almost ten months post-vaccination, on July 15, 2019. Exhibit 3 at 8. The purpose of the visit was to establish care and undergo an annual physical. While noting at the time of this visit that Petitioner complained of right shoulder pain which she attributed to the flu vaccine she received in September 2018, her primary care provider ("PCP") appeared to question that conclusion, given the length of time which had passed between vaccination and when Petitioner sought care. It was also noted that Petitioner was offered formal physical therapy which she refused in favor of a home exercise program. *Id.*

Other than this record and later-provided histories, plus the allegations made in the Petition and her affidavit, Petitioner has provided no evidence to support her claim, such as affidavits from family, friends, or co-workers or other documentation. Additionally, she offered no explanation of her condition during the ten-month period from September 2018 until she sought care or evidence in July 2019.

Narratives of post-vaccination pain provided closer in time to the vaccine's administration date would typically be afforded more weight than assertions made when filing the Petition. *See Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). And it is not uncommon for claimants alleging a SIRVA injury to delay care a bit, and/or to first recount a history of pain even a month or two after vaccination. Here, however, Petitioner first provided this information to her PCP almost *ten months* post-vaccination, and only four months before the medical records were requested to support Petitioner's claim. Thus, it is more properly characterized as a *current* assertion made by Petitioner contemporaneously with the advancement of this claim – and therefore the kind of assertion not typically given much weight, if any. *See* Section 13(a)(1) (instructing that a special master may not find compensation appropriate "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion").

In order, to prevail in this case, Petitioner needed to provide preponderant evidence to support her assertion that she suffered a SIRVA as alleged. Petitioner's ten-month delay in seeking treatment, and lack of evidence regarding the onset of her pain and alleged symptoms during this ten-month period, suggest the claim cannot succeed. I provided Petitioner the opportunity to provide the evidence to establish a vaccine-related injury as she alleges. Petitioner has failed to do so.

IV. Conclusion

To date, and despite ample opportunity, Petitioner has failed to file preponderant evidence to support her allegations of a right SIRVA injury following receipt of the flu vaccine on September 24, 2018. Petitioner was informed that failure to file sufficient evidence, to support her claim would be treated as either a failure to prosecute this claim or as an inability to provide supporting documentation for this claim. Accordingly, this case is DISMISSED. The clerk shall enter judgment accordingly.[5]

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[5] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by the parties' joint filing of notice renouncing the right to seek review.